REMARKS

In the Office Action, the Examiner argues that Applicant's amendment filed January 31, 2007 was not fully response to the prior Office Action because newly submitted claims 119-142 were directed to an invention that is independent and distinct from the invention originally claimed. The Examiner contends that the subject matter of claims 119-142 was previously subject to a restriction requirement, and was not elected. Based on that contention, the Examiner has withdrawn claims 119-142 as being drawn to a non-elected invention.

Applicants respectfully disagree with the Examiner's withdrawal of the claims, because claims 119-142 are drawn to the same subject matter as the elected invention as set forth in the Restriction Requirement issued September 29, 2004; Applicants' response filed December 23, 2005; and the Office Action issued March 25, 2005.[1] Namely, claims 119-142 are all drawn to methods for administration by injecting or delivering the substance into the intradermal space or compartment of the skin resulting in improved pharmacokinetic effects as compared with subcutaneous delivery. To clarify the subject matter of the elected invention, Applicants have summarized the discussion relating to the elected invention in the Restriction Requirement, Applicants' December 2005 response, and the March 2005 Office Action below.

In the Restriction Requirement, claims 1-118 were subject to a restriction requirement under 35 U.S.C. § 121 to one of the following groups:

> Group I: Claims 1-37, drawn to a method of delivering a substance into an intradermal space at a depth of 0.3-2 mm, classified in class 604, subclass 506.
>
> Group II: Claims 38-45, drawn to a microneedle, classified in class 604, subclass 264.
>
> Group III: Claims 46-64, drawn to a method of contacting a subject's skin with a device to deliver a bioactive substance to a dermal space, classified in class 604, subclass 500.

[1] For economy of expression, Applicants will refer to the Restriction Requirement issued September 29, 2004 as the "Restriction Requirement"; Applicants' response filed December 23, 2004 as the "Applicants' December 2004 Response"; and the Office Action issued March 25, 2005 as the "March 2005 Office Action".

Group IV: Claims 65-74, drawn to a method of injecting a substance into the dermis to achieve improved systemic absorption relative to subcutaneous injection, classified in class 604, subclass 506.

Group V: Claims 75-96, drawn to a method of injecting growth hormone, heparin, or dopamine receptor agonist into the dermis to obtain systemic absorption, classified in class 604, subclass 507.

Group VI: Claims 97 and 98, drawn to an electroporation or thermal poration device classified in class 604, subclass 20.

Group VII: Claims 99-118, drawn to a method of administering a substance to the dermis to achieve improved systemic absorption as compared to bolus subcutaneous administration, classified in class 604, subclass 506.

In addition to the restriction to one of the above claim groups, the Examiner required Applicants to elect a single disclosed species for prosecution on the merits from among the species identified on page 4, paragraph 3 of the Restriction Requirement.

In Applicants' December 2004 Response, Applicants provisionally elected, with traverse, to prosecute the claims of Group VII (claims 99-118), drawn to methods of administering a substance to the dermis to achieve improved systemic absorption as compared to bolus subcutaneous administration. Applicants also argued that the subject matter of the claims of Groups IV, V, and VII merited examination in a single application, and submitted that a search and examination of such groups would not be a serious burden on the Examiner. *See* pages 13-14 of Applicants' response filed December 23, 2004. In addition, Applicants elected the species drawn to heparin for examination on the merits.

In the March 2005 Office Action, the Examiner reconsidered the restriction and agreed with Applicants that claim groups IV, V and VII were all directed to a method of administering a substance intradermally. Accordingly, the Examiner examined the claims of those groups, claims 65-96 and 99-118, on their merits.

Similarly here, claims 119-142 introduced in Applicants' January 31, 2007 amendment are also drawn to methods of administering a substance intradermally, and are not drawn to a non-elected invention. For instance, Claims 119-135 and originally elected claims are similarly directed to improved systemic absorption upon intradermal injection relative to absorption produced upon injecting the substance subcutaneously. Moreover, in contrast to the Examiner's contention, by specifying the needle outlet's depth and exposed

height in claims 119-142, Applicants have *not* changed the elected invention, but have merely clarified the needle configuration used to administer the substance to the intradermal space or compartment. Accordingly, Applicants respectfully submit that withdrawal of claims 119-142 was in error and request reconsideration.

Applicants respectfully request that the remarks made herein be entered into the record of the instant application.

CONCLUSION

Applicants respectfully request that the Examiner consider the remarks made herein. Withdrawal of all rejections, and an allowance is earnestly sought. The Examiner is invited to call the undersigned attorney if a telephone call could help resolve any remaining items.

Respectfully submitted,

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Date: June 18, 2007

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